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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/574,461	11/30/1995	ANTHONY D. BARONE	16528X-0155-	6825
28315	7590	01/10/2005	EXAMINER	
BANNER & WITCOFF LTD., ATTORNEYS FOR AFFYMETRIX 1001 G STREET, N.W. ELEVENTH FLOOR WASHINGTON, DC 20001-4597			PONNALURI, PADMASHRI	
		ART UNIT		PAPER NUMBER
		1639		
DATE MAILED: 01/10/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	08/574,461	BARONE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Padmashri Ponnaluri	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 06 October 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-8 and 10-56 is/are pending in the application.
- 4a) Of the above claim(s) 16-36 is/are withdrawn from consideration.
- 5) Claim(s) 10-15 and 50-56 is/are allowed.
- 6) Claim(s) 1-8, and 37-49 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

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### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/6/04 has been entered.
2. The amendment and response filed on 10/6/04 have been fully considered and entered into this application.

#### ***Status of Claims***

3. Claims 1-8, 10-56 are currently pending in this application.
4. Claims 16-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/5/97.
5. Claims 1-8, 10-15 and 37-56 are currently being examined in this application.
6. The indicated allowability of claims 1-8, 37-39 is withdrawn in view of the following rejections.

#### ***Priority***

7. This application claims priority to provisional application 60/003,726, filed on 9/13/95.

#### ***Withdrawn Claim Rejections***

8. The rejection of claim 10 as being indefinite, has been withdrawn in view of the amendment.

9. The written description and scope enablement rejections of claims 40-56 has been withdrawn in view of applicants response.

***New Rejections***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-8, 39-49 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. The method steps for measuring critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In the instant claimed method is drawn to monitoring the polymer array synthesis. However, the instant claim methods do not recite how the presence of unbound biological polymers as indicator of the efficiency of the synthesizing step. Does applicants mean that the unbound biological polymer of the instant claimed method is compared with standards or biological polymer synthesized compared to a different method. Applicants are requested to include method steps used to measure the efficiency of the synthesis.

12. Claims 1-8, 39-49 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The method of measuring to determine the efficiency of the synthesis step. It is not clear, how measuring the unbound polymer is an indication of efficiency of synthesis step. The efficiency of synthesis step depends on several variables, such as reaction conditions i.e., reagents used, the cleavable linkers used, and solid

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support surface, reaction conditions or the different cleavable linkers. Thus, applicants are requested to include the method step, how the efficiency of the synthesis step is measured. And further, there is no correlation to the claimed method and the method steps, i.e., the instant claim is drawn to ‘a method of monitoring polymer array synthesis on a solid substrate’, and the last step of the method is ‘measuring the presence of diverse unbound polymer as indicator of efficiency of the synthesizing step.’ Applicants are requested to amend the claim to clearly recite the method steps.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-8, 39-49 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,679,773 (Holmes).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

The instant independent claims briefly recite a method of monitoring polymer array synthesis on a solid substrate comprising: I) synthesizing a pre-selected array of diverse

polymers connected to cleavable linkers on a solid support; ii) cleaving the diverse polymers from the substrate; iii) measuring the presence of unbound diverse polymers as an indicator of the efficiency of the synthesizing step.

Holmes teaches methods for solid phase synthesis of organic molecules. Holmes teaches use of linking groups, which are useful in solid phase synthesis of high-density arrays. Holmes et al teach that improvements to the coupling chemistry used in the light directed methods of VLSIPS process. Holmes in column 19 teaches that the methods provide for synthesis of polymers and determination of synthesis fidelity, which occurs on a solid substrate. Holmes teaches that the claimed method has polymer attached to the solid support through a cleavable linker (i.e., see column 19). Holmes teaches a labeled polymer is synthesized on a solid support (refers to the instant claim labeled polymer), and subsequent cleavage of the labeled polymer from the solid support (refers to the labeled unbound polymer of the instant claims) and comparison with known standards provides a confirmation of synthesis fidelity (refers to the instant claim step iii) (i.e., see column 19). Holmes teaches that the label refers to a marker is detected by spectroscopic methods (i.e., see column 20). Holmes teaches that following the synthesis of the attached labeled polymer, the fidelity of synthesis can be determined by cleaving labeled polymer from the solid support, subjecting the labeled polymers to high performance liquid chromatography (refers to claims 4, 47-48) and comparing the resultant chromatogram with a chromatogram from a standard which is synthesized by alternative method (i.e., see column 22) (refers to the instant claimed method of monitoring the polymer array synthesis). Holmes clearly anticipates the claimed invention.

***Allowable Subject Matter***

15. Claims 10-15, 50-56 are allowed.

***Response to Arguments***

16. Applicant's arguments with respect to claims 40-56 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PADMASHRI PONNALURI  
PRIMARY EXAMINER

Padmashri Ponnaluri  
Primary Examiner  
Art Unit 1639

08 January 2005